DELIVERY APPARATUS FOR USE DURING A SURGICAL PROCEDURE AND METHOD OF USING THE SAME

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present invention relates to, and is entitled to the benefit of the earlier filing date and priority of, Application No. 60/394,233, filed on July 9, 2002, which is herein incorporated by reference as if fully set forth.

FIELD OF THE INVENTION

[0002] The present invention relates to a delivery apparatus. In particular, the present invention is directed to a delivery apparatus for use in a surgical procedure wherein at least one fastener is delivered to a site of the surgical procedure by the delivery apparatus.

BACKGROUND

[0003] An aneurysm is a ballooning of the wall of an artery resulting from the weakening of the artery due to disease or other conditions. Left untreated, an aneurysm may rupture, resulting in loss of blood through the rupture and death.

[0004] Aortic aneurysms are the most common form of arterial aneurysm and are life threatening. The aorta is the main artery which supplies blood to the circulatory system. The aorta arises from the left ventricle of the heart, passes upward and bends over behind the heart, and passes down through the thorax and abdomen. Among other arterial vessels branching off the aorta along its path, the abdominal aorta supplies two side vessels to the kidneys, the renal arteries. Below the level of the renal arteries, the abdominal aorta continues to about the level of the fourth lumbar vertebrae (or the navel), where it divides into the iliac arteries. The iliac arteries, in turn, supply blood to the lower extremities and perineal region.

[0005] Repair of an aortic aneurysm by surgical means is a major operative procedure. Substantial morbidity accompanies the procedure, resulting in a protracted

recovery period. Further, the procedure entails a substantial risk of mortality. While surgical intervention may be indicated and the surgery carries attendant risk, certain patients may not be able to tolerate the stress of such surgery. It is, therefore, desirable to reduce the mortality and morbidity associated with surgical intervention.

[0006] In recent years, methods have been developed to attempt to treat an aortic aneurysm without the attendant risks of intra-abdominal surgical intervention. Among them are inventions disclosed and claimed in Kornberg, U.S. Patent No. 4,562,596 for Aortic Graft, Device and Method for Performing an Intraluminal Abdominal Aortic Aneurysm Repair; Lazarus, U.S. Patent No. 4,787,899 for Intraluminal Graft Device, System and Method; and Taheri, U.S. Patent No. 5,042,707 for Intravascular Stapler, and Method of Operating Same.

[0007] Although in recent years certain techniques have been developed that may reduce the stress, morbidity, and risk of mortality associated with surgical intervention to repair aortic aneurysms, none of the systems that have been developed provide methods and apparatus directed to the repair of thoracic aneurysms. Treatment of patients with thoracic, thoracoabdominal or upper abdominal aortic aneurysms is difficult. The open operative procedures have a high mortality rate with an associated serious and frequent morbidity as well. Accordingly, the endovascular approach holds much promise as an alternative treatment method. Use of fasteners that penetrate the prosthetic graft as well as the full thickness of the aortic wall will undoubtedly facilitate an endovascular approach. Such an approach carries with it the possibility of causing bleeding through the holes in the aorta; moreover, any penetrating method has the risk of puncturing a lung and causing a pneumothorax. While a small air leak from a traumatized lung would necessitate insertion of a tube in the chest, this minor procedure would be far less traumatic than an open aneurysm repair. Nonetheless, minimizing lung trauma as well as minimizing blood loss into the chest, are desirable attributes of an endovascular approach to treatment of patients with thoracic, thoracoabdominal or upper abdominal aortic aneurysms.

[0008] It is therefore an advantage of some, but not necessarily all, embodiments

of the present invention to provide methods and apparatus for the surgical repair of aneurysms. It is another advantage of embodiments of the present invention to provide methods and apparatus for the surgical repair of thoracic, thoracoabdominal, and upper abdominal aneurysms.

[0009] Additional advantages of various embodiments of the invention are set forth, in part, in the description that follows and, in part, will be apparent to one of ordinary skill in the art from the description and/or from the practice of the invention.

SUMMARY OF THE INVENTION

[0010] Responsive to the foregoing challenges, Applicant has developed an innovative delivery apparatus for use in a surgical procedure. According to at least one embodiment of the present invention, a delivery apparatus for performing a surgical component comprises: a flexible catheter capable of assuming an angular configuration at a predetermined time during the surgical procedure; a penetration apparatus disposed within the catheter, the penetration apparatus further comprises a first end having a tip, and a second end that is substantially free; and at least one fastener in communication with the penetration apparatus.

[0011] According to at least another embodiment of the present invention, the delivery apparatus for performing a surgical component comprises: a flexible catheter capable of assuming an angular configuration at a predetermined time during the surgical procedure; a penetration apparatus disposed within the catheter, the penetration apparatus further comprises a first end having a tip, and a second end that is substantially free; at least one fastener in communication with the penetration apparatus; and a sealant material associated with at least a portion of the fastener.

[0012] According to at least one further embodiment of the present invention, the delivery apparatus for performing a surgical component comprises: a flexible catheter capable of assuming an angular configuration at a predetermined time during the surgical procedure; a penetration apparatus disposed within the catheter, the penetration apparatus further comprises a first end with a tip that is an open core needle

and a second end that is substantially free; at least one fastener disposed within the penetration apparatus; and a sealant material associated with at least a portion of the fastener.

[0013] According to at least one additional embodiment of the present invention, the method for performing a surgical procedure at a surgical site, which comprises the steps of: advancing a delivery apparatus to the surgical site; activating the delivery apparatus to contact the surgical site; advancing the delivery apparatus wherein the delivery apparatus creates an aperture at the surgical site; and releasing a fastener to the surgical site, wherein at least one portion of the fastener further comprises a sealant material.

[0014] It is to be understood that both the foregoing general description and the following detailed description are exemplary and exemplary only, and are not restrictive of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] In order to assist the understanding of this invention, reference will now be made to the appended drawings, in which like reference characters refer to like elements.

[0016] Figure 1 is a cut-away pictorial view of an embodiment of the present invention at a surgical site.

[0017] Figures 2 and 3 are cut-away pictorial views of embodiments of the present invention advancing towards the surgical site.

[0018] Figure 4 is a cut-away pictorial view of an embodiment of the tip penetrating through a surgical component and a vessel.

[0019] Figure 5 is a cut-away pictorial view of the advancement of a fastener through a surgical component and a vessel.

[0020] Figure 6 is a cut-away pictorial view of the deployment of a fastener of the

present invention.

[0021] Figure 7 is a cut-away pictorial view of an embodiment of the flexible catheter retracted from the inner catheter.

[0022] Figure 8 is a cut-away pictorial view of the retraction of the delivery apparatus with the fastener deployed at the surgical site.

[0023] Figure 9 is a cut-away pictorial view of an example embodiment of the delivery apparatus.

[0024] Figures 10 and 11 are cut-away pictorial views of example embodiments of the present invention advancing towards the surgical site.

[0025] Figure 12 is a cut-away pictorial view of an embodiment of the tip penetrating through a surgical component and a vessel.

[0026] Figure 13 is a cut-away pictorial view of the advancement of a fastener through a surgical component and a vessel.

[0027] Figure 14 is a cut-away pictorial view of the deployment of a fastener of the present invention.

[0028] Figure 15 is a cut-away pictorial view of the retraction of the delivery apparatus with the fastener deployed at the surgical site.

[0029] Figure 16 is a cut-away pictorial view of example embodiments of fasteners used in the delivery apparatus.

[0030] Figure 17 is a cut-away pictorial view of an embodiment of a fastener deployed at a surgical site.

[0031] Figure 18 is a cut-away pictorial view of a further embodiment of the present invention penetrated through a surgical component and a vessel.

[0032] Figures 19, 20, and 21 are cut-away pictorial views of the present

invention deploying fasteners.

[0033] Figures 22 and 23 are cut-away pictorial views of the retraction of the delivery apparatus after deploying an fastener to a surgical site.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0034] Reference will now be made in detail to embodiments of the present invention, examples of which are illustrated in the accompanying drawings. With reference to Figs. 1-8, the delivery apparatus **10** is shown in a pictorial cross-section. The delivery apparatus **10** may comprise a flexible catheter **12**, a penetration apparatus **16**, a tip **18** of the penetration apparatus **16**, and at least one or more fasteners **20**. The penetration apparatus **16** may have a hollow core or a solid core. In some embodiments, the delivery apparatus **10** may also comprise an inner catheter **14** within the flexible catheter **12**, as shown in Fig. 1.

[0035] The delivery apparatus **10** advances through a vessel (not shown) to a surgical site within the vessel to insert at least one or more fasteners **20** through a surgical component **100** and a vessel **200**. The advancement of the delivery apparatus **10** is through, but not limited to, the extension of the delivery apparatus **10** by a mechanical mechanism, by hand, or by any other suitable means.

[0036] In an example embodiment of Fig. 1, the flexible catheter **12** has an end portion **50** capable of assuming an angular configuration. In at least one embodiment, the end portion **50** may be manipulated by using a pull wire (not shown), as disclosed in U.S. Patent Application No. 09/783,313 filed on Feb. 15, 2001, which is herein incorporated in its entirety by reference. The delivery apparatus **10**, as a whole, is flexible such that it may be multi-directional to enable maneuvering through tortuous vessels. In further example embodiments, the flexible catheter **12** articulates wherein an end portion of the flexible catheter **12** assumes an angular configuration, as illustrated in Fig. 1. In other example embodiments, an expandable member such as, but not limited to, a balloon, or additional articulation of the flexible catheter **12** to create an appositional force, or any other suitable means may be used in conjunction with the

flexible catheter **12** (not shown). In the embodiment of Fig. 1, a surgical component **100** is attached to a vessel **200**. In alternative embodiments, the surgical component may be attached to another surgical component, or tissue attached to tissue, or attachment of any combination of surgical components, vessels, and tissues.

[0037] An embodiment of the method of the delivery apparatus **10** will now be described with reference to Figs. 2-8. In Fig. 2, the delivery apparatus **10** is advanced to the surgical site through the vessel (not shown). The inner catheter **14** along with the penetration apparatus **16** are advanced either simultaneously or in sequence such that they extend from the flexible catheter **12**. The inner catheter **14** and/or the penetration apparatus **16** may be advanced further until applying sufficient pressure on the surgical component **100** to push the surgical component **100** against the vessel **200**, as shown in Fig. 3. In further example embodiments, with the advancement of the inner catheter **14** and/or the penetration apparatus **16**, the flexible catheter **12** abuts the opposite side of the surgical component **100**, also depicted in Fig. 3. The tip **18** of the penetration apparatus **16** is then activated and advanced to create an aperture in the surgical component **100** and the vessel **200**, illustrated in Fig. 4. The penetration apparatus **16** and the tip **18** advance to penetrate the surgical component **100** and the vessel **200** to create an aperture there through. The activation of the tip **18** and the penetration apparatus **16** occurs by, but is not limited to, mechanical or electrical mechanisms or any other appropriate mechanism. Through the aperture, the fastener **20** extends spanning the surgical component **100** and the vessel **200**, as shown in Fig. 5. One or more fasteners may be deployed from the hollow core of the penetration apparatus **16** or deployed from around an outside surface of the penetration apparatus **16**.

[0038] In example embodiments of the present invention, the fastener **20** is associated with a sealant material such as, but not limited to, a plug of the surgical component, an absorbable substance, an occluding substance, or any other suitable material or any combination thereof. In further example embodiments, the absorbable substance may be, but not limited to, Gelfoam® or Surgicil®. The use of the sealant substance may be beneficial in preventing or minimizing bleeding when inserted into the surgical component and the vessel with or without the fastener.

[0039] The fastener **20** in Fig. 6 is flexible applying a force to secure the surgical component **100** to the vessel **200**, as disclosed in the following U.S. Patents and Patent Applications: U.S. Provisional Patent Application No. 60/181,230, filed February 9, 2000; U.S. Patent Application No. 09/442,768, filed November 18, 1999; U.S. Patent Application No. 09/213,233, filed December 17, 1998, now U.S. Patent No. 5,997,556; U.S. Patent Application No. 08/958,524, filed October 27, 1997, now U.S. Patent No. 5,957,940; U.S. Patent Application No. 08/896,415, filed July 18, 1997, now U.S. Patent No. 5,944,750; and U.S. Provisional Patent Application No. 60/051,209, filed June 30, 1997. The subject matter of the patents and patent applications are incorporated herein specifically by reference.

[0040] In various example embodiments, the tip **18** of the penetration apparatus **16** comprises an open core needle, a leading edge, a heating probe, a radio frequency tip, a boring tip, a coring tip, an optical fiber, or any other suitable means capable of penetrating through the surgical component and/or tissues or vessel. In Fig. 6, the tip **18** penetrating through the surgical component **100** and the vessel **200** is an open core needle tip. Because the open core needle tip is sharp and pointed, penetration occurs with the needle's advancement. In further example embodiments, the tip **18** is interchangeable such that the tip is integral with the penetration apparatus **16** and able to accommodate varying thicknesses and densities of the surgical site. In other example embodiments, the tip **18** may be an extension of the penetration apparatus **16** such that the tip **18** and the penetration apparatus **16** are a unitary structure and/or of unitary construction.

[0041] In Fig. 7, the fastener **20** within the inner catheter **14** starts to assume its unconstrained configuration but may be precluded from doing so completely by the inner catheter **14**. With the withdrawal of the inner catheter **14**, the fastener **20** assumes an unconstrained configuration. As shown in Fig. 8, the penetration apparatus **16** and the inner catheter **14** are retracted toward the flexible catheter **12**, thereby deploying the fastener **20** to secure the surgical component **100** to the vessel **200**. In some embodiments, this method may be repeated at various locations of the surgical site to deploy multiple fasteners.

[0042] Further example embodiments of the present invention are illustrated in Figs. 9-14. In Figs. 9-14, the delivery apparatus **10** may be advanced through the lumen of a surgical component **100**, such as, but not limited to, a prosthetic graft, which is positioned adjacent to the vessel **200**. In Fig. 9, the delivery apparatus **10** comprises a flexible catheter **12**, a penetration apparatus **16**, a tip **18** of the penetration apparatus **16**, and at least one fastener **20**. The penetration apparatus **16** is advanced to the surgical site such that the tip **18** contacts the surgical component **100**, as illustrated in Fig. 10.

[0043] In Fig. 10, the penetration apparatus **16** is advanced such that it extends to contact the surgical component **100**. The penetration apparatus **16** still advances to push the surgical component **100** against the vessel **200**, as shown in Fig. 11. The penetration apparatus **16** continues such that the tip **18** penetrates the surgical component **100** and the vessel **200**, as depicted in Fig. 12. Once the tip **18** has sufficiently penetrated the surgical component **100** and the vessel **200**, the fastener **20** is activated, illustrated in Fig. 13. In Fig. 13, the activation of the fastener **20** sequentially dispenses the fastener or a plurality of fasteners at the surgical site. Upon retraction of the penetration apparatus **16**, the fastener **20** assumes a secondary orientation, securely attaching the surgical component **100** to the vessel **200** as shown in Fig. 13. In alternative embodiments, the fastener **20** is positioned within, around, or in conjunction with the penetration apparatus **16**. In Fig. 14, the fastener **20** is illustrated in an unconstrained configuration outside the vessel **200**. The fully released fastener spans the surgical component **100** and the vessel **200**, as shown in Fig. 15.

[0044] In various example embodiments illustrated in Fig. 16, the fastener **20** may be a double coil fastener **24** with minimal separation **26** between the coils. In some embodiments, the separation **26** may be, but is not limited to, about 0.5mm to about 0.2mm. The fastener **20** may also have barbs **28** located along the length of the fastener. The barbs **28** may be oriented so that the barb located on a portion of the coil outside the surgical component **100** and the vessel **200** will likely snag on an outside surface of the surgical component **100** and/or the vessel **200**, as shown in Fig. 17.

[0045] In Figs. 18-23, an embodiment of the present invention depicts the delivery apparatus **10** with a coiled coil fastener, the fastener **20**, being inserted through the surgical component **100** and the vessel **200**. The insertion is by the tip **18** of the penetration apparatus **16**. As the coil emerges from the penetration apparatus **16**, it may assume its unconstrained coiled coil shape as seen in Fig. 19. In the embodiment shown in Figs. 18-23, the flexible catheter **12** is retracted back to the penetration apparatus **16** until the flexible catheter **12** contacts the penetrated surgical component **100**. As the penetration apparatus **16** is withdrawn back into the flexible catheter **12**, the fastener **20** extrudes from the penetration apparatus **16**, as seen in Fig. 21. As the penetration apparatus is withdrawn further, the coiled coil fastener **20** releases from the sheath **16** to assume its coiled coil configuration, depicted in Fig. 22. The flexible catheter **12** is then dislodged from the surgical component **100** such that the fastener **20** transverses the surgical component **100** and the vessel **200** with a coiled coil on both the extraluminal portion of the vessel **200** and the intraluminal portion of the surgical component **100**.

[0046] Numerous characteristics and advantages have been set forth in the foregoing description, together with details of structure and function. The novel features are pointed out in the appended claims. The disclosure, however, is illustrative only, and changes may be made in detail, especially in matters of shape, size and arrangement of parts, within the principle of the invention, to the full extent indicated by the broad general meaning of the appended claims that are expressed. Further, it will be apparent to those skilled in the art that variations and modifications of the present invention can be made without departing from the scope or spirit of the invention.